EXHIBIT B

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1
            IN THE UNITED STATES DISTRICT COURT
2
        FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
                   CHARLESTON DIVISION
4
    IN RE: ETHICON, INC., PELVIC ) MASTER FILE NO.
    REPAIR SYSTEM PRODUCTS
                            ) 2:12-MD-02327
5
                                   ) MDL NO. 2327
    LIABILITY LITIGATION
6
    THIS DOCUMENT RELATES TO THE
    FOLLOWING CASES IN THE WAVE 1
    OF MDL 200:
    LISA THOMPSON, et al.,
                                   ) CASE NO.
8
                                   ) 2:12-cv-01199
                   Plaintiff,
9
    V.
10
    ETHICON, INC., ET AL.,
11
                   Defendants.
12
          DEPOSITION OF KIMBERLY H. ALLISON, M.D.
13
14
   DATE:
                        THURSDAY, MARCH 17, 2016
15
                        12:58 P.M.
   TIME:
16
   LOCATION:
                        STANFORD PARK HOTEL
17
                        100 El Camino Real
18
                        Menlo Park, California
19
20
21
    Reported by:
22
    LUCY CARRILLO-GRUBBS, RMR, CRR, RPR, CRP, CSR
    License No. 6766
23
24
25
```

Page 2	Page 4
1 APPEARANCES 2 FOR PLAINTIFF:	1 BE IT REMEMBERED THAT, pursuant to the laws
2 FOR PLAINTIFF: 3 P. LEIGH O'DELL, ESQUIRE	2 pertaining to the taking and use of depositions,
Law Offices of BEASLEY ALLEN CROW METHVIN PORTIS	3 and on THURSDAY, MARCH 17, 2016, commencing at the
4 & Miles, P.C. 218 Commerce Street	4 hour of 12:58 p m. thereof, at the STANFORD PARK
5 Montgomery, AL 36103	5 HOTEL, 100 El Camino Real, Menlo Park, CA
Tel: 334.269.2343 6 Fax: 334.954.7555	6 California, before me, LUCY CARRILLO-GRUBBS, CRP,
Email: Leigh.Odell@BeasleyAllen.com	7 RMR, CRR, RPR, CSR No. 6766, a Certified Shorthand
7 FOR DEFENDANTS:	8 Reporter in and for the State of California,
8	9 personally appeared
S. PETER VOUDOURIS, ESQUIRE 9 Law Offices of TUCKER ELLIS, LLP	10
950 Main Avenue, Suite 1100	11 KIMBERLY H. ALLISON, M.D.
10 Cleveland, Ohio 44113 Tel: 216.592.5000	12
11 Fax: 216.592.5009	13 being called as a witness by the Defendants, who,
Email: peter.voudouris@tuckerellis.com	14 having been by me first duly sworn, was thereupon
TRACI L. SHAFROTH, ESQUIRE	15 examined and interrogated as hereinafter set forth.
13 Law Offices of TUCKER ELLIS, LLP	16 -oOo-
One Market Plaza, Steuart Tower 14 Suite 700	17 (Defendants' Exhibit No. 1, 2, 3, 4 and 5 were
San Francisco, CA 94105	
15 Tel: 415.617.2400 Fax::415.617.2409	18 marked for identification.) 19 -o-
16 Email: traci.shafroth@tuckerellis.com	
17 -oOo- 18	20 EXAMINATION
19	21 BY MR. VOUDOURIS:
20 21	Q. Can you state your full name for the
22	23 record, please?
23 24	24 A. Kimberly Heller Allison.
25	25 MR. VOUDOURIS: Before we start today, I just
Page 3	Page 5
1 INDEX	¹ want to put something on the record.
2 Examinations Page	As you know, Ms. O'Dell, it was our
3 BY MR. VOUDOURIS 4	³ position that since Dr. Allison has never given a
4 BY MS. O'DELL 79	4 deposition in an Ethicon case or any kind of TVT
5 FURTHER EXAMINATION BY MR. VOUDOURIS 84	5 case, and does have a report that has a general
6	6 opinion section, that we believe that we are
7	7 entitled to a three-hour expert deposition on her
8	8 general opinions.
9 EXHIBITS	9 You have objected to that in two of the
10 No. Description Page	10 e-mails, both to Mr. Snowden, I believe one was on
11 1 Amended Notice of Deposition of 4	11 March 15th, and another one on March 16th, where
12 Kimberly H. Allison	12 you said we will not make Dr. Allison available for
13 2 Rule 26 Expert Report of Kimberly H. 4	a general expert three-hour deposition.
14 Allison, M.D.	14 Is that still your position today?
15 3 Curriculum Vitae 4	15 MS. O'DELL: Yes, it is. The agreement in the
16 4 Facts or Data Considered in Forming 4	16 MDL between counsel for Ethicon and the Plaintiffs'
17 Opinions	
18 5 Spreadsheet labeled Exhibit C 4	seeing committee has even that for emperes who
20 5 Spicausifica faucieu Exhibit C 4	18 have been disclosed as general conserver arrest-
19 6 Evpert report of Tari Longgara M.D. 17	have been disclosed as general causation experts,
19 6 Expert report of Hannes Vogel M.D. 54	that they are subject to a three-hour deposition on
20 7 Expert report of Hannes Vogel, M.D. 54	that they are subject to a three-hour deposition on their general opinions.
20 7 Expert report of Hannes Vogel, M.D. 54 21 8 Color photo 64	 that they are subject to a three-hour deposition on their general opinions. For experts who have not been disclosed as
 20 7 Expert report of Hannes Vogel, M.D. 54 21 8 Color photo 64 22 9 Document titled Final Tissue Report 77 	 that they are subject to a three-hour deposition on their general opinions. For experts who have not been disclosed as a general causation expert but only as a case
20 7 Expert report of Hannes Vogel, M.D. 54 21 8 Color photo 64 22 9 Document titled Final Tissue Report 77 23	 that they are subject to a three-hour deposition on their general opinions. For experts who have not been disclosed as a general causation expert but only as a case specific expert, like Dr. Allison, the agreement of
20 7 Expert report of Hannes Vogel, M.D. 54 21 8 Color photo 64 22 9 Document titled Final Tissue Report 77 23 24	that they are subject to a three-hour deposition on their general opinions. For experts who have not been disclosed as a general causation expert but only as a case specific expert, like Dr. Allison, the agreement of the parties was limited to two hours per case.
20 7 Expert report of Hannes Vogel, M.D. 54 21 8 Color photo 64 22 9 Document titled Final Tissue Report 77 23	 that they are subject to a three-hour deposition on their general opinions. For experts who have not been disclosed as a general causation expert but only as a case specific expert, like Dr. Allison, the agreement of

- ¹ Dr. Allison has not been disclosed as a general
- ² causation expert. She has only been disclosed as a
- ³ case specific expert; and, therefore, for her
- 4 deposition in the Thompson, Phelps and Barker
- ⁵ cases, the limitation is two hours per case.
- MR. VOUDOURIS: And you understand from
- previous e-mails that that is not the defense's
- opinion and we're going to file a motion on that
- issue, just so you know. 9
- 10 Second part of housekeeping, prior to last
- 11 evening we were anticipating taking your deposition
- 12 in at least four case specific cases, maybe a
- 13 fifth, and we just were informed last night that
- 14 you would no longer be giving case specific
- opinions in the Deborah Joplin case; is that
- 16 correct?
- 17 MS. O'DELL: That is correct.
- 18 MR. VOUDOURIS: Okay.
- 19 Q. Do you understand, Dr. Allison, that to be
- 20 correct?
- 21 A. Yes.
- 22 Q. And you're also not going to be giving any
- 23 expert testimony in the Maria --
- 24 MS. O'DELL: It's Quijano.
- 25 MR. VOUDOURIS: Quijano.

- 1 spreadsheet was to assist you in offering your case
- ² specific opinions; is that correct?
- A. Yes.
- Q. And the Joplin case and the Quijano case,
- ⁵ based on Exhibit C, there was no mesh in those two
- cases: is that correct?
- A. There was no mesh on a slide from their
- cases, no.
- Q. Did you ever see any mesh in those two
- 10 cases?
- 11 A. No. I was only provided with some
- 12 available cervical tissue and things that were not
- 13 related.
- Q. And yet you issued case specific reports
- in those two cases; is that correct, regarding the
- 16 TVT?
- 17 A. Just based on medical record review, yes.
 - Q. So I'm correct in that statement?
- 19 A. Yes, just based on medical record review,
- 20 yes.
- 21 Q. Is that something that you do at Stanford
- 22 when you're at work, give opinions on matters where
- you don't have the pathology?
- 24 A. Sometimes we do based on review of
- pathology records, only in discussion at like a

Page 7

- MS. O'DELL: And as -- Dr. Allison will not be
- 2 giving case specific opinions in the Quijano case,
- 3 based on the decision of counsel.
- I would say further --
- MR. VOUDOURIS: And I have copies of everything
- 6 if you want to see it.
- Go ahead.
- 8 MS. O'DELL: Further, Dr. Allison has been
- 9 disclosed not only in the Thompson, Phelps and
- 10 Barker matters, and -- and I'm counsel of record in
- 11 those matters, but she's also been disclosed as a
- 12 case specific expert in numerous cases that are
- 13 represented by Blazen, Game, Birch & Girard, and
- 14 those cases, as I understand, have been deferred to
- 15 another setting that's not yet been decided.
- 16 BY MR. VOUDOURIS:
- 17 Q. Dr. Allison, I've handed you what we've
- 18 marked as Defendants' Exhibit C, can you identify
- 19 that for us?
- A. Yes. This is the spreadsheet of my case
- 21 specific findings on the pathology and review of
- 22 records.
- 23 Q. You created this spreadsheet?
- 24 A. Yes.
- 25 Q. And the purpose of creating this

- 1 tumor board, if slides aren't available, say, does
- ² this make sense, given the pathology that was
- ³ recorded.
- Q. Other than a tumor board, do you do that
- as part of your daily practice at Stanford?
- A. In terms of writing a pathology report?
- Q. Right, without pathology slides.
- A. So actually we do. So we sometimes give
- second opinions on outside reviews, we do that a
- lot. So they come in with slides and a pathology
- report and sometimes they don't send all of the
- 12 slides available on a case. And so we say that
- some of our opinions are based on report only.
- 14 Q. Okay.
- 15 Maybe I wasn't clear enough in my
- question, and I don't want to interrupt you.
- 17 By the way, we're going to be here for a
- few hours today, let's not try and interrupt each
- other, because it's tough for the court reporter,
- 20 okav?
- 21 A. I understand.
- 22 Q. All right.
- I meant at Stanford, other than getting a 23
- consult -- and actually the example you gave me is
- someone did send you pathology slides.

Page 10 Page 12 1 At Stanford when you're there working Q. Do you remember how many cases or patients ² every day and you're reading breast pathology, do 2 those involved? 3 you ever issue a report without looking at the A. Ten to 15. I could -- again, I could look 4 histology? ⁴ at my records. A. No. Usually we receive some of the 5 Q. All right. And then you'll let us know? 6 histology. 6 Q. We're here to take your deposition in the A. Yes. 8 case involving an Ethicon product named TVT and the Q. Have you testified in court? A. No. 10 Have you ever been deposed in those types 10 Q. Do you have any plans to? 11 of cases before? 11 A. No. 12 A. No, I've not. 12 Q. I'm sorry? Q. When was the last time you were deposed in 13 A. No. 13 14 I'll call it a mesh case? 14 Q. The three patients that we're going to be A. Last year sometime, I don't recall the talking about over the next two days, I just want 16 exact date. to make sure, have you seen any of those patients? 17 Q. All right. A. No. 18 18 2015? Q. Treated them in any way? 19 A. I believe so. 19 A. No. 20 Q. Talked to any of their doctors? 20 Q. Do you remember what time of year? A. I could check my records and tell you 21 21 Q. Read any of the other expert reports in 22 that. 22 23 Q. Okay. 23 those cases? 24 Will you do that for us? A. I think they've been made available to me, 25 A. Sure. ²⁵ but I may have read parts of some. Page 11 Page 13 Q. All right. 1 Q. I'm sorry, you have to keep your voice up. What was the product that you were A. I may have read parts of some of them. ³ involved with in that deposition? 3 Q. In what case or cases? A. Bard slings. 4 A. I believe Barker. Q. And have you -- you've given other Q. You read an expert report in Barker? 6 deposition testimony against Bard; is that correct? 6 A. Yes. A. Correct. Q. Do you know who it was authored by? 8 8 Q. How many times have you testified in cases A. Felix. 9 9 against Bard? Q. Do you know Dr. Felix? 10 MS. O'DELL: Just to clarify, Peter, you're 10 A. No. 11 talking about like a day-long deposition or are you 11 Q. Do you know him by reputation? 12 talking about the number of cases? 12 13 MR. VOUDOURIS: Well, we can break that down. 13 Q. Do you know what type of pathologist he Q. How many depositions have you given in 14 is? 15 15 cases against Bard? A. OB-GYN. 16 MS. O'DELL: And I would just clarify the Q. Okay. 17 17 record, those depositions were done in composite so And would I be correct in saying that your 18 it was one deposition, it was multiple cases, so I 18 specialty in pathology is breast? 19 don't know -- your question's a little unclear. 19 A. And GYN. 20 THE WITNESS: Yeah. 20 Q. And we'll talk about your experience with So I think there have been two 21 GYN in a moment. 22 22 depositions, different time points; is that Any other reports? 23 correct? And there were multiple patients, 23 A. I read the Longacre report that was -- I ²⁴ multiple cases in each deposition. don't believe it was case specific, maybe it was. 25 BY MR. VOUDOURIS: 25 Q. Do you know Dr. Longacre?

Page 14 Page 16 1 A. Yes. No. I don't think I have. 2 Q. When did you read Dr. Felix's report? Q. I imagine you do. 3 What is her position at Stanford? A. I was just perusing it. It was made 4 A. She's a professor of pathology. ⁴ available last night, so I was just perusing it an 5 Q. And you are an associate professor? ⁵ hour ago. 6 Q. Okay. A. Associate professor. 6 7 Did you finish it? Q. So in terms of the hierarchy, she's higher up on the totem pole, so to speak, than you? A. I did not read it in-depth. 9 9 A. Yes, she's been there a lot longer. Q. Okay. 10 10 Q. Right. Did you have any disagreements with it, as 11 11 you sit here today? What's her position at Stanford? 12 A. Well, yes, of course I did. I mean, we A. Professor of pathology. She has many 13 positions, I mean, many other roles, have different opinions on the -- on the cases, ¹⁴ administrative-wise. 14 yes. 15 15 Q. Right. Q. Okay. 16 16 A. So... How do you differ from Dr. Felix's 17 Q. Is she known as a GYN pathologist at opinions? 18 Stanford? A. Well, shall we go through them step by 19 A. She is, and we codirect the breast and GYN step or can I see the report so we can discuss them and I can --²⁰ fellowship together. 21 21 Q. I'll talk about that in a minute. Q. Did you bring it with you? 22 22 Do you trust Dr. Longacre? A. No. 23 23 A. Yes. Q. Okay. 24 Q. Do you believe she's a competent and 24 How about Dr. Longacre? ²⁵ capable GYN pathologist? A. I didn't bring that one with me either. Page 15 Page 17 A. Yes. 1 1 MR. VOUDOURIS: Okay. 2 Q. Would you send patients to her to have Well, you're in luck today. 3 their GYN path read? (Defendants' Exhibit No. 6 was marked for A. Yes. 4 identification.) BY MR. VOUDOURIS: Q. You value her opinion? 6 A. Yes. Q. Dr. Allison, we hand you what we've marked 7 Q. And she's well respected in the GYN as Defendants' Exhibit 6. This is the copy of the pathology community? general report of Dr. Longacre, that you told us 9 A. Yes. you were provided. 10 Q. Any other reports? 10 A. Yes. 11 A. I'm not recalling. I definitely read 11 Q. And did you read it? 12 12 those two. A. I read the majority of this, yes. 13 13 Q. Is there anything else you specifically Q. Anything else that you can remember? 14 A. No. disagree with in Dr. Longacre's report? 15 MS. O'DELL: Feel free to go through it and --Q. All right. 16 Any expert reports in those three cases? and if you need a minute to review it. 17 MS. O'DELL: Other than the one she just THE WITNESS: So there are some things I agree 18 mentioned. with in the way that she stated them, and, you 19 MR. VOUDOURIS: I'm sorry. 19 know, they're very subtle ways that we disagree 20 Q. Plaintiff's expert reports. 20 that I think are important. A. Besides the pathologist ones? BY MR. VOUDOURIS: Q. Well, you named two defense pathologists, Q. Well, let's stop and go through this and 23 tell me, because you had an opportunity to read it, 23 you named Dr. Felix and Dr. Longacre, who you know 24 very well. 24 what you disagree with her that is important.

25

A. Yeah, yeah, yeah.

25

A. Okay, so I agree that mesh erosion -- she

- ¹ says, on page 7: "Mesh erosion with TVT slings is
- ² a rare complication. This is a known
- ³ complication."
- ⁴ I agree it's a known complication. I
- 5 think it's a little more common than rare. I don't
- ⁶ know how she's defining rare there.
- Q. Well, how do you define more common?
- 8 A. Well, she hasn't given a percent, I
- 9 mean --
- Q. No, my question is to you.
- 11 A. Oh, okay.
- Q. How do you define more common?
- A. Well, the literature that I've reviewed
- 14 look -- said complication rates like erosion and,
- 15 you know, up to ten percent of patients, so one in
- ¹⁶ ten doesn't seem that rare to me.
- Q. Are you talking about a TVT product?
- A. I'm talking about mesh products in
- 19 general.
- $^{\rm 20}$ $\,$ $\,$ Q. Do you know what the rate is for the TVT
- 21 product?
- A. Specifically I've been thinking of these
- 23 as a group, so five percent.
- Q. Do you know or are you just guessing?
- A. There's a variety of percentages in the

- gs is 1 Q. Can you tell me what literature supports
 - ² your contention that the risk of erosion with TVT

Page 20

- ³ is between five and ten percent?
- 4 A. No. I can't point you to the specific.
- ⁵ This is a very long list of articles and I can't
- ⁶ point to one in particular off the top of my head
- 7 that has the specific findings.
- I really read through the literature. I
- ⁹ have a general picture of the rates of
- complications and the types of complications that
- occur with mesh, based on looking at it all, and
- then I also focused in on the pathology findings.
- Q. You understand you're here to give
- 14 specific case opinions regarding a TVT-O product
- and a TVT product, correct?
 - A. Correct.

16

- Q. And as we sit here today, you can't tell
- ⁻⁸ us what the rate of exposure is -- or erosion, I'm
- 19 sorry, for a TVT product; is that correct?
- A. I gave you a percentage of five to ten
- ²¹ percent, my estimate.
- Q. Yeah.
- But that's an estimate for mesh in
- general, correct?
- MS. O'DELL: Object to the form.

Page 19

1

- ¹ literature, so if I give you a number, I'm sure you
- ² could point to another article that would give a
- ³ different percentage.
- 4 Q. Okay.
- But my question was, five percent, are you
- 6 just guessing?
- A. I'm estimating between five and ten
- ⁸ percent.
- ⁹ Q. Dr. Allison, I hand you what we've marked
- ¹⁰ as Defendants' Exhibit 4.
- 11 Can you identify that for us, please?
- A. This is the literature list, data that I
- 13 used in consideration of my opinion.
- Q. Your opinions in the three cases that
- ¹⁵ we're going to talk about?
- A. Yes, including these three cases.
- Q. And you created that list?
- 18 A Ves
- Q. And I understand some of the things you
- ²⁰ found and others were provided to you by
- ²¹ plaintiff's counsel, is that accurate?
- MS. O'DELL: Object to the form.
- THE WITNESS: Yes, we both were contributing
- $^{\rm 24}\,$ articles to this list and I looked at them.
- 25 BY MR. VOUDOURIS:

- Page 21
- 2 BY MR. VOUDOURIS:
- ³ Q. Well, is there -- are there specific
- ⁴ literature out there that gives specific rates of

THE WITNESS: Which includes TVT.

- ⁵ complications for TVT?
- ⁶ A. I'm sure it's in all of this.
- Q. Can you tell us which ones? This is your
- 8 list, not mine.
- 9 A. No. I -- I cannot point to the exact one.
- 10 I focused on pathology findings in -- in even more
- depth, so I'm a pathologist. I'm not a
- 12 urogynecologist. I don't quote percentages of
- complications to patients.
- I look at findings under the microscope
- ⁵ and in the gross room. I review pathology
- literature and then I review in a broader sense,
- 17 the rest of the literature that's related to what
- 18 kinds of complications these patients get.
- And then in a specific case, I don't need to know the percentage rate. I need to know, you
- know, does this patient have one of these
- ² complications that has been described in the
- literature, and do I see pathologic findings that
- ²⁴ make sense in that setting.

25

Q. So the answer to my question is, no, you

- ¹ can't tell us on your list what specific articles
- ² give specific rates of various complications
- ³ regarding the TVT products?
- ⁴ A. That's correct.
- ⁵ MS. O'DELL: Object to the form.
- 6 BY MR. VOUDOURIS:
- ⁷ Q. Dr. Allison, we handed you what is
- ⁸ Defendants' Exhibit 2, I believe.
- ⁹ Can you identify that for the record,
- 10 please?
- 11 A. This is my expert report.
- Q. And it contains your background and
- ¹³ qualifications, correct?
- ¹⁴ A. Yes.
- Q. A section on general opinions, which your
- ¹⁶ counsel has prohibited us from asking about, and
- ¹⁷ then a section on case specific; is that correct?
- MS. O'DELL: That is not correct. I've not
- ¹⁹ prohibited you from asking about the general
- ²⁰ principles that she's relied on in rendering her
- ²¹ opinions in these cases.
- What I have stated on the record
- ²³ repeatedly today and by e-mail is that
- ²⁴ Dr. Allison's not been disclosed as a general
- ²⁵ causation expert, as you're well aware.

- Page 24
- ¹ in the breast pathology, but I originally applied
- for the job which was posted as a GYN pathologist,
 and they hired me based on my expertise in both
- 4 breast and GYN. They've needed people to fill in
- 5 more on the breast service, and so that's what I've
- 6 done.
- ⁷ Q. You came to Stanford in January of 2013, I
- 8 believe?
- 9 A. Yes.
- Q. Since January 2013, have you signed out
- ¹¹ any GYN path at Stanford?
- 12 A. No, I have not.
- 13 I've done frozen sections on GYN
- ¹⁴ pathology, which is intraoperative consultations.
 - Q. Right, but that's for cancer, correct?
- A. No. They're not all for cancer.
- Q. What else are they for?
 - A. Intraoperative evaluations are for "what
- ¹⁹ is this" questions, a surgeon wants to know what
- 20 they have in the OR, immediately, and so they'll
- send tissue to us to freeze and rapidly tell them.
- Q. How often do you do that?
- A. Every single day that I'm on service.
 - Q. And have you ever asked to evaluate a
- ²⁵ frozen section regarding vaginal tissue while at

Page 23

- You're welcome to ask her about anything
- ² in her report.
- 3 BY MR. VOUDOURIS:
- 4 Q. You do mention here that you're the
- ⁵ codirector at the Stanford Breast/GYN Pathology
- ⁶ Fellowship; is that accurate?
- 7 A. Yes.
- ⁸ Q. Is there a director?
- 9 A. A director that --
- Q. At Stanford -- sorry.
- 11 A. Teri Longacre.
- Q. So Teri Longacre sits above you in that
- 13 position; is that correct?
- MS. O'DELL: Object to the form.
- 15 THE WITNESS: Correct, she was there before I
- ¹⁶ came to Stanford in 2013. She had that fellowship
- ¹⁷ established, and when I arrived, she asked me to
- 18 codirect it with her.
- 19 BY MR. VOUDOURIS:
- Q. She was part of your hiring process,
- 21 correct?
- 22 A. Yes.
- Q. Now, at Stanford, do you review GYN
- 24 pathology?
- A. Not currently. They have needed me more

- 1 Stanford?
- A. Vaginal tissue, there's a lot of GYN
- ³ frozen, but vaginal tissue is not an intraoperative
- 4 consultation
- 5 Q. So the answer to my question would be no?
- 6 A. I think it would be no, yes.
- ⁷ Q. When was the last time you looked at -- or
- 8 signed out, I'm sorry, a report on vaginal tissue
- 9 that was not a frozen section?
- MS. O'DELL: Are you talking about in the -- in
- 11 the course of her clinical --
- 12 MR. VOUDOURIS: Yes.
- MS. O'DELL: -- practice?
- 14 MR. VOUDOURIS: I'm sorry.
- 15 THE WITNESS: Probably would have been in 2012,
- 16 before I came. I -- you know.
- 17 BY MR. VOUDOURIS:
- Q. To the best of your knowledge, have you
- 19 ever looked at mesh from a TVT product as part of
- 20 your clinical practice?
- A. I've looked at explanted mesh as part of
- 22 my clinical practice in the past. I was not paying
- 23 attention during those years I was looking at those
- 4 cases with, you know, what type of procedure it had
- 25 been removed from, so I don't know.

O. You don't know?

2 A. I don't know.

³ Q. I apologize, we got a little sidetracked.

We were going through Dr. Longacre's

⁵ report, and you were up to page 7, I believe.

A. Yes.

⁷ Q. Do you agree with everything that she said

8 before page 7?

A. I would really rather not have to disagree

10 on a case on a statement-by-statement basis with my

11 colleague. I'm happy to talk about my case

12 specific findings and if you have disagreements

 13 with them, to go through them, but it's putting me

¹⁴ in a very awkward position.

I -- we all disagree with each other in

¹⁶ practice on occasion, but this is a very awkward

position for me to be in.

8 Q. Well, it's going to be an awkward position

19 regardless, Dr. Allison. So is there anything that

²⁰ you disagree with up to page 7 in Dr. Longacre's

21 report?

MS. O'DELL: And, Dr. Allison, if you -- if

23 you -- if he's asking you to go through every line

²⁴ and word, then feel free to just take a few minutes

25 and to do that.

1 A. Yes.

2 Okay.

3 MS. O'DELL: And what's the question, Counsel?

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Page 29

4 MR. VOUDOURIS: Can you check, please?

5 (The Reporter read back as follows:

6 "Question: So is there anything

7 that you disagree with up to page

8 7 in Dr. Longacre's report?")

THE WITNESS: Okay. So we want to start at the

o beginning of what looks like her opinions at page

11 2. "So foreign material, however inert, when

12 implanted into the human tissue typically invokes

13 an inflammatory response in the initial phase,

14 which can be associated with acute inflammation,

15 but generally evolves into a more chronic tissue

16 response with associated lymphocytes, mast cells

17 and macrophages."

So I agree that that occurs, but then over

¹⁹ time that typically resolves.

20 BY MR. VOUDOURIS:

Q. Typically resolves regarding what?

A. The chronic inflammation, the foreign body

23 giant cell type reaction continues, so I agree with

24 that.

21

I agree that the acute inflammatory

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¹ THE WITNESS: I need a break.

MS. O'DELL: Okay. Let's go off the record.

³ (Recess taken from 1:34 p.m. to 1:56 p.m.)

4 MR. VOUDOURIS: It's -- we've been off the

⁵ record now for how long, court reporter?

⁶ THE REPORTER: From 1:34 to 1:56.

⁷ BY MR. VOUDOURIS:

⁸ Q. And, Dr. Allison, you went outside to

⁹ collect yourself, correct?

10 A. Yes.

Q. Are you ready to proceed?

¹² A. Yes.

13 O. Okay.

And you understand the defense didn't put

15 you in this position, okay? You're going to be

offering testimony that's going to be directly

adverse to and opposite to the chairman of thedepartment of GYN pathology at Stanford.

Do you understand that?

²⁰ A. Yes.

19

22

Q. And are you ready to proceed?

A. Yes.

Q. Okay.

We're going through Dr. Longacre's report,

25 right?

¹ response typically disappears, and then it's

² followed by chronic inflammatory cells consisting

³ of lymphocytes, plasma cells, mast cells,

4 macrophages, occasionally eosinophils.

⁵ Q. Dr. Longacre (sic), I'm sorry, I don't

6 mean to interrupt, but my original question was

⁷ what you disagree with.

8 A. Okay.

9 Q. You're going through here and you're

10 agreeing with what she's saying. So to make it

11 easier on you and to make this process shorter, is

12 there anything that you disagree with up to and

13 including page 7 in Dr. Longacre's report?

MS. O'DELL: I'd just object to the question,

15 she -- the form of the question you've just asked,

you asked her to go through the report line by

line, that's what she's doing.

And it's not fair to ask a general

⁻⁹ question if she agrees with every word and comma of

20 the report. And if you've asked her that question,

she's free to go through it line by line.

MR. VOUDOURIS: Ms. O'Dell, that's fine, and

please stop the speaking objections so we can get

24 through this.

Q. Go ahead.

- A. So I disagree that the chronic
- ² inflammatory response continues, but I agree that
- 3 the foreign body giant cell type response --
- 4 Q. What's your basis --
- 5 A. -- doesn't --
- 6 Q. -- for disagreeing with Dr. Longacre on
- 7 that point?
- 8 A. I think she just hasn't gone into much
- ⁹ detail in terms of she's left out the lymphocytic
- 10 response as the component that continues. So she's
- 11 not being specific as to the type of -- the exact
- 12 type of inflammatory response that continues over
- 13 time or doesn't continue over time.
- Q. Are you basing your disagreement with her
- ¹⁵ because of your review of explanted TVT meshes?
- A. I'm basing -- well, what I'm saying is
- 17 she's not being specific in terms of the type of
- 18 inflammation that continues in a chronic
- ¹⁹ inflammatory response that's abnormal. There are
- 20 many statements in here that I agree with.
- Q. That wasn't my question.
- A. Can you repeat your question?
- Q. I want to know where you have disagreement
- ²⁴ with Dr. Longacre's opinions that are part of her
- 25 expert report that's in front of you, that you told

- 1 you disagree with that?
 - 2 MS. O'DELL: She's free to answer.
 - ³ THE WITNESS: Can finish up my answer?
 - 4 MS. O'DELL: Yeah. You're free to answer when

Page 32

Page 33

- ⁵ you'd like to. You can consider the question and
- ⁶ you're free to answer with whatever explanation
- ⁷ you'd like to give.
- 8 THE WITNESS: The complications are clear and
- 9 she lists them here, pain, dyspareunia, mesh
- 10 exposure, those have occurred in the patients that
- ¹¹ we are going to be talking about.
- 12 BY MR. VOUDOURIS:
- O. Each of which occur in less than five
- ¹⁴ percent of patients, correct?

15

24

- A. But they occurred in these patients.
- Q. That wasn't my question.
- Do you disagree with that sentence?
 - A. I guess it depends on how low you think
- ¹⁹ five percent is. Certainly if you're the patient
- who that happens to you don't think that that's an
- ²¹ insignificant complication.
- Q. That's not my question, Dr. Allison.
- 23 We'll be here for a long time.
 - Do you disagree with that sentence?
- A. It's not a black and white, you know,

- ¹ me that you read.
- A. Okay. Well, I'm going to keep going line
- ³ by line, then.
- Q. That's fine.
- 5 A. Just so that we're detailed and we're
- ⁶ making sure that I'm going over it all.
- Q. And, please, when you get to a place where
- ⁸ you disagree with her, tell me the basis for your
- ⁹ disagreement.
- 10 A. Okay.
- Q. Whether it's experience, whether it's
- ¹² literature, you tell me.
- A. Okay. Okay, I'm continuing to read and
- 14 I'm agreeing with some of the statements she's
- ¹⁵ saying about integration of fibrosis into the mesh
- ¹⁶ as a part of the process that is expected to occur.
- Q. What page are you on?
- ¹⁸ A. I'm on 4.
- Q. Do you see where she quotes a 17-year data
- ²⁰ demonstrating a high cure rate and very low
- ²¹ complication rate with the TVT sling?
- ²² A. I do.
- Q. Do you disagree with that?
- ²⁴ A. I think --
- Q. That's a simple question, Dr. Allison, do

- ¹ agree or disagree. It's -- I think those
- ² complications are significant. I think five
- ³ percent is, you know, not an insignificant number
- 4 and so I agree with the sentence. Very low I guess
- 5 is a subjective term.
- 6 Q. Do you agree that the complication rates
- ⁷ including pain, dyspareunia, mesh exposure, each of
- 8 which occur in less than five percent of patients
- 9 with TVT according to the 17-year study, do you
- 10 agree with that?
- 11 MS. O'DELL: Object.
- 12 THE WITNESS: Yes.
- MS. O'DELL: Object to the form.
- 14 BY MR. VOUDOURIS:
- Q. Continue.
- 16 MS. O'DELL: With what?
- MR. VOUDOURIS: I don't think it's that
- 18 confusing, is it, reading line by line and telling
- us where you disagree with Dr. Longacre.
- THE WITNESS: She states: "The FDA stated that
- 21 polypropylene is safe and effective in the
- 22 treatment of stress urinary incontinence."
- Although I know the FDA also has warnings about the use of mesh.
 - BY MR. VOUDOURIS:

- Q. That's not the question and the process
- ² that we're going through here, Dr. Allison.
- The process is, you're going through here
- 4 line by line, and I'll let you do that, and you're
- 5 going to tell us where you disagree with the head
- 6 of GYN pathology at Stanford.
- A. This isn't black and white, so to say I
- 8 agree or disagree, I want to tell you my thoughts
- ⁹ on the sentences that she's got in here. And so
- 10 I'm trying to express my opinions and my knowledge
- 11 about these statements she's making.
- Q. Actually, it is black and white because
- 13 this is black and white, these statements, and in
- 14 trial it's going to be very black and white,
- 15 Dr. Allison.
- 16 So do you disagree with the statement that
- 17 Dr. Longacre has in bold, "The FDA has stated that
- polypropylene is safe and effective in the
- treatment of stress urinary incontinence"?
- MS. O'DELL: Object to the form of the
- 21 question.
- 22 BY MR. VOUDOURIS:
- 23 Q. Do you disagree with that sentence?
- A. I would say it is not safe and effective
- 25 in all patients.

- Q. Do you disagree with that statement? 1
- 2 MS. O'DELL: And if you don't have an opinion
- ³ about it, you're welcome to say that.
- MR. VOUDOURIS: Objection.
- 5 THE WITNESS: I mean, I told you my opinion.
- 6 MR. VOUDOURIS: Stop, stop, excuse me --
- 7 THE WITNESS: You're trying to make me say --
- 8 THE REPORTER: I'm sorry, I can't take two of
- ⁹ you at the same time.
- 10 BY MR. VOUDOURIS:
- 11 Q. Go ahead, Dr. Allison.
- 12 MS. O'DELL: She's answered your question.
- 13 MR. VOUDOURIS: I don't think she has.
- 14 Q. Go ahead.
- 15 MS. O'DELL: I believe she has.
- 16 THE WITNESS: I told you what I would say
- 17 instead of this statement, so it's not that I a
- 18 hundred percent disagree with the statement, I
- 19 would state it in a different way.
- 20 BY MR. VOUDOURIS:
- Q. Have you ever contacted the FDA and told
- 22 them that you don't think that polypropylene is
- 23 safe and effective in a few patients or however you
- ²⁴ worded it?
- 25 A. No, and I don't think Dr. Longacre

¹ contacted them either to ask them if it was safe

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- ² and effective.
- O. That wasn't the question.
 - The question was you, have you ever
- contacted the FDA --
- A. No. Of course not.
- Q. -- and told them that polypropylene is not
- safe and effective in the treatment of stress
- urinary incontinence?
- 10 A. No.
- 11 Q. Continue, please.
- 12 A. So she says: "There's no correlation
- between the degree of fibrosis and inflammation in
- the presence of pain and/or mesh exposure."
- - So there are parts I agree with and parts
- I disagree with about that statement.
- The degree of fibrosis and inflammation, I
- agree that that hasn't been systematically linked
- to patients with pain versus patients without pain
- or patients with exposure versus patients without
- 21 exposure.
- 22 However, I don't think that that means
- that the patients who have those symptoms, that it
- wasn't caused by the presence of the mesh and the
- fibrosis and inflammation in those patients.
- Page 35
- Q. And is that based on your experience?
- 2 A. My experience as a pathologist?
- 3 O. Yes.
- A. Yeah, my experience looking at 80 to 100
- of these cases of explants and reading the
- ⁶ literature and understanding these are known
- complications of this procedure.
- Q. You've looked at 80 to 90 what?
- 9 A. Mesh explant tissues.
- 10 Q. Okay.
- 11 How many TVT explant tissues have you
- 12 looked at?
- A. Again, you asked me that question earlier,
- and I don't know the exact percentage.
- 15 Q. Do you have any idea what the percentage 16 is?
- 17 A. No.
- 18 Q. And in the -- I'm sorry, what was the
- number, 80 to 90 of mesh explants?
- 20 MS. O'DELL: I think it's what she said.
- 21 THE WITNESS: I said 80 to 100, yes.
- 22 MR. VOUDOURIS: Okay.
- 23 Q. Where did you get those cases from?
- 24 A. Well, in my prior practice at University
- ²⁵ of Washington, I probably saw ten to 20, just

- 1 explants being removed.
- And then I saw I think 60 or so cases when
- ³ I was first working on the Bard product litigation,
- 4 that were sent to me just to review. Some of them
- ⁵ weren't even cases I was opining on, just to look
- 6 at what kinds of findings there were in mesh
- ⁷ explants, so that I could have more exposure to it.
- Q. I've had an opportunity to look at some of
- ⁹ your depositions in the Bard cases, and you
- 10 testified that when you were at University of
- 11 Washington you saw maybe ten to 12; is that
- 12 accurate?
- A. Sure, that's between ten and 20.
- 14 Q. All right.
- Of those ten to 20 patients, did all of
- 16 them experience pain?
- A. So when you're making a surgical pathology
- 18 report, you're cognizant of what symptom -- why --
- 19 why something's being removed when the clinician is
- 20 asking you to explain a symptom.
- So if there was a biopsy for a mass and
- 22 they want to know what is the mass, we explain to
- 23 them what is the mass.
- So for -- for most foreign material
- ²⁵ removal, the clinician already knows this is the

- A. Correct.
- Q. And they were provided to you by

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- ³ plaintiffs?
- ⁴ A. Yes.
- ⁵ Q. Okay.
- 6 Is it fair for me to assume that all of
- ⁷ those patients complained of pain?
- A. I think many of them did, yes.
- ⁹ Q. Okay.
- As we sit here today, can you tell me any
- 11 of them who didn't?
- A. I believe some were probably just for
- ³ erosion or other dysfunction.
- Q. Do you know that or are you just guessing?
- A. I don't -- I don't have a spreadsheet of
- ¹⁶ all of the cases I've ever looked at and have a --
- ¹⁷ of course I'm just guessing.
- ¹⁸ Q. All right.
- A. These are all educated guesses you're
- ²⁰ asking me to make.
- Q. What statement were you at, or sentence?
- A. The degree of fibrosis and inflammation.
- ²³ So I think I addressed that one.
- Q. Anything else in 4 you agree with?
- MS. O'DELL: Object to form.

- ¹ reason I'm removing this. I've made a decision as
- ² the surgeon that I think this is causing a problem,
- ³ whether it's pain, erosion, dysfunction of some
- 4 kind. It's time to take this out, this foreign
- ⁵ body out.
- 6 And so -- so as a pathologist, your job is
- ⁷ to document that something was removed for them.
- ⁸ It's not the same question as is being asked of me
- ⁹ here, in these cases. It's linking the pathology
- ¹⁰ with the clinical symptoms.
- 11 Q. Okay.
- 12 I believe my question was pretty simple,
- 13 the ten to 12 cases that you looked at at
- 14 University of Washington of mesh explants, did all
- 15 of those women complain of pain?
- MS. O'DELL: Objection to the form.
- 17 THE WITNESS: We didn't always have the
- 18 clinical information about why things were being
- 19 removed.
- 20 BY MR. VOUDOURIS:
- Q. So you don't know?
- A. I don't know.
- Q. All right.
- The other meshes you've looked at have all
- ²⁵ been part of litigation, correct?

- Page 41 THE WITNESS: I'm not going to go through each
- ² sentence in great detail because we'll be here way
- 3 too long. I think it would be better if I just
- 4 scanned through and said which ones I disagree with
- ⁵ in a major way. And I think I reserve the right to
- 6 go back and look at some of the details and say
- ⁷ whether I agree or disagree.
- 8 BY MR. VOUDOURIS:
- 9 Q. Dr. Allison.
- 10 A. Yes.
- Q. The task that you've been asked to do, and
- 12 Ms. O'Dell has asked you to do too, is to go
- 13 through here line by line and tell us where you
- 14 disagree with the head of GYN pathology at
- ¹⁵ Stanford, Dr. Longacre.
- A. Should I read the entire statement to you,
- 17 then?
- Q. Yeah, keep reading. You don't have to
- 19 read out loud, read to yourself.
- 20 A. Okay.
- Q. And when you get to a place where you
- 22 disagree with Dr. Longacre, you tell us, and you
- 23 tell us the basis for that disagreement.
- MS. O'DELL: And, Dr. Allison, you're free to
- 25 read out loud if you'd like to, you're free to

- 1 respond to the question any way that you would
- ² choose, and you're free to take all the time you
- 3 would like to take, and we've got, you know, two
- 4 hours on the record and that's what it's going to
- 5 be.
- 6 MR. VOUDOURIS: Well, we took 20 minutes
- ⁷ because Dr. Longacre (sic) had to go outside and
- 8 compose herself. And then she's come back in and
- 9 now we're going through this process. And please
- 10 stop with the speaking objections.
- 11 Stop, please.
- MS. O'DELL: I can say whatever I want to.
- MR. VOUDOURIS: You can, but --
- 14 MS. O'DELL: I will.
- MR. VOUDOURIS: -- what you're doing is not
- 16 proper.
- Q. So go ahead, Dr. Allison.
- MS. O'DELL: It certainly is. It's proper for
- ¹⁹ me to make objection.
- And take the time that you need,
- 21 Dr. Allison.
- MR. VOUDOURIS: No one has told her to do
- 23 anything else.
- THE WITNESS: So she mentions on page 4 that a
- ²⁵ pathologist -- "The cumulative literature data on

- I -- I do think that dyspareunia that
- ² begins at the time of mesh implantation and was not

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- ³ present in the same way beforehand is linked to the
- 4 mesh material that was implanted.
- Q. What literature is on your alliance list
- 6 that supports your disagreement with Dr. Longacre?
- A. There's plenty of literature that
- ⁸ discusses these erosions and dyspareunia and pain
- ⁹ that are -- I mean, she states in her very report
- ¹⁰ that those are known adverse outcomes. She states
- 11 that up earlier. This low complication rate
- 12 includes pain, dyspareunia and mesh exposure.
- Q. That's not my question.
- A. So she's read the same literature as me.
 - Q. She comes to very different conclusions
- 16 than you do, doesn't she?
- A. They're subtly different.
- Q. Subtly different?
- 19 A. Uh-hmm.

15

- Q. Do you think Dr. Longacre's going to label
- 21 them as subtly different?
- A. Is that a question?
- Q. Yes, it is.
- 24 A. Yes.
- Q. Keep reading, please.

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- 1 mesh explants does not enable a pathologist to
- ² reliably and reproducibly correlate the pathology
- ³ findings in mesh explant materials to any specific
- 4 symptom."
- 5 BY MR. VOUDOURIS:
- 6 Q. And I'm sorry, you're on page 4, where?
- A. About two lines -- five lines from the
- 8 bottom, six lines from the bottom.
- 9 Q. All right.
- A. And then she goes on to say: "Although
- 11 there are several studies that attempt to compare
- 12 the histology findings in mesh material removed
- 13 from symptomatic and asymptomatic patients, valid
- 14 comparisons cannot be drawn and clinical
- ¹⁵ pathological correlations cannot be made on the
- 16 basis of current data."
- I find it hard to argue that an erosion in
- ¹⁸ a patient who -- vaginal erosions are
- 19 extraordinarily rare, and they're much more common
- ²⁰ in patients who have these mesh material implanted.
- 21 And, you know, they recur in the patients who have
- 22 mesh material implanted.
- So I -- I do think that the literature
- ²⁴ allows us to reproducibly correlate those kind of
- ²⁵ findings with that specific symptom.

- Page 45
 Would you tell me when I have a half hour
- ² left, please?

1

- A. So it looks like we disagree with mesh
- 4 degradation.
- 5 Q. What page are you on?
- 6 A. Five.
- 7 O. Whereabouts?
- 8 A. Second full paragraph.
- 9 Q. What sentence?
- 10 A. "Several studies including some by Ethicon
- 11 have suggested there may be degradation of the mesh
- 12 following implantation. These data when taken in
- 13 aggregate are not compelling arguments at this
 - 4 point in time.
- 15 "First, it is not clear that degradation
 - occurs to any extent in vivo. Second, if it
- 17 does" --
- Q. Do you disagree with that statement?
- A. I -- I do disagree with that statement.
- Q. And is the basis for that your experience?
- A. Yes. I've seen what has been described by
- others in the literature as evidence of degradation
- 23 in the cases that I've looked at.
- 24 Q. Okay.
- And those are -- the cases you're talking

- ¹ about are the cases that were referred to you by
- ² plaintiffs' attorneys, correct?
- 3 A. Yes.
- ⁴ Q. And the people who have talked about this,
- ⁵ or written about it in the literature, are
- ⁶ Dr. Iakovlev and some of the other plaintiffs'
- ⁷ experts?
- 8 A. Dr. Iakovlev has --
- 9 MS. O'DELL: Object to form.
- 10 THE WITNESS: -- published about this, yes.
- 11 BY MR. VOUDOURIS:
- 12 Q. Okay.
- A. There are not many pathologists that have
- ¹⁴ published about this in the literature, and he is
- 15 one of them.
- Q. Anyone else you can think of?
- A. Besides Iakovlev?
- ¹⁸ Q. Yes.
- ¹⁹ A. Klosterhalfen did some, but Iakovlev's
- ²⁰ work has been probably the most detailed in terms
- ²¹ of what I can correlate with under the microscope.
- Q. Is it fair to say that it's his theories
- ²³ on degradation upon which you rely for your
- ²⁴ specific case opinions?
- MS. O'DELL: Object to the form.

- BY MR. VOUDOURIS:
- Q. Have you ever dictated in a path report
- ³ that you saw degradation of mesh as part of your

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- ⁴ clinical practice?
- A. His papers were describing this entity in
- ⁶ the last several years, so no, I've not.
- Q. Have you told Dr. Longacre that you
- 8 believe mesh in vivo degrades?
- A. We do not speak -- we have not spoken
- ¹⁰ about this litigation.
- Q. Okay. Continue.
- A. On page 6 she talks about nerve twigs in
- 13 the first paragraph, and mentions: "The presence
- ¹⁴ of nerves or nerve twigs in and around the mesh
- ¹⁵ material does not necessarily (and, in fact, is
- ¹⁶ unlikely to) reflect the presence of increased pain
- ¹⁷ sensation."
- And I am of the opinion that the
- integration of nerve fibers into the scarring
- ²⁰ around these mesh fibers more likely than not
- contributes to the pain in these patients, and
- ²² would emphasize that there are plenty of sensory
- ²³ nerves in that area that it is likely to affect.
- Q. All right.
- This is your opinion, but see, as an

- THE WITNESS: It's not his theories, per se,
- ² but the evidence he presents for the tree barking
- ³ effect that I can see under the microscope.
- 4 BY MR. VOUDOURIS:
- ⁵ Q. Other than you qualifying it a different
- 6 way, am I correct?
- ⁷ MS. O'DELL: Object to the form.
- 8 THE WITNESS: Can you state it again for me?
- 9 (The Reporter read back as follows:
- ¹⁰ "Question: Other than you qualifying
- it a different way, am I correct?")
- 12 THE WITNESS: Before that.
- MS. O'DELL: I think she meant the statement
- ¹⁴ before that.
- 15 (The Reporter read back as follows:
- 16 "Question: Is it fair to stay that
- it's his theories on degradation
- upon which you rely for your
- specific case opinions?")
- MS. O'DELL: Object to the form.
- THE WITNESS: It's the -- yeah, the evidence
- 22 that he presents, yes, I wouldn't call them
- 23 theories. He's published about them and provided
- ²⁴ evidence that was accepted in peer reviewed
- ²⁵ literature.

- 1 expert, you have to have a basis for your opinion.
- 2 So what's the basis for that opinion?
- 3 MS. O'DELL: Object to the form.
- 4 You asked her what she disagreed with,
- 5 she's told you.
- 6 MR. VOUDOURIS: Yeah.
- 7 MS. O'DELL: So don't lecture her about being
- ⁸ an expert.
- 9 MR. VOUDOURIS: I've asked you three times now,
- 10 maybe four, to stop.
- 11 MS. O'DELL: Just --
- MR. VOUDOURIS: Just stop.
- Q. Go ahead, Dr. Allison.
- MS. O'DELL: Just fine, I'll keep making my
- 15 objections. Stop lecturing the witness.
- 16 THE WITNESS: Your question is why do I think
- 17 I'm qualified -- I'm a pathologist.
- 18 BY MR. VOUDOURIS:
- Q. No, it wasn't my question.
- You're a breast pathologist, right, you're
- 21 not a GYN pathologist?
- A. I'm trained in GYN and breast pathology,
- 23 I'm trained in pathology as well.
- Q. And you do not --
- A. Nerves are not unique --

Page 52 Page 50 Q. -- practice GYN pathology at Stanford; is 1 literature that you have on that chair, can you 2 that correct? 2 point to me that supports your opinion on that 3 A. Nerves are not unique to GYN. 3 regard? Q. Do you practice GYN pathology at Stanford? A. I mean, other pathologists have noticed A. You already asked me that question, and 5 the presence of these nerve fibers and come to 6 I'm not currently practicing GYN pathology at 6 similar conclusions around the mesh and in the 7 Stanford. fibrosis. MR. VOUDOURIS: Could you go back, please, when Q. That wasn't my question. 9 I asked her about the basis of her opinion. Do you need the court reporter to read it MS. O'DELL: Counsel, if you would let her 10 back to you? 11 finish her responses, don't interrupt her, please. 11 MS. O'DELL: Just --12 12 (The Reporter read back as follows: THE WITNESS: Well, you were asking me about 13 13 the literature. "Answer: On page 6 she talks about 14 nerve twigs in the first paragraph, 14 MS. O'DELL: Excuse me. 15 15 and mentions: 'The presence of THE WITNESS: So I was telling you about the 16 nerves or nerve twigs in and around 16 literature. 17 17 MS. O'DELL: She answered your question. the mesh material does not necessarily 18 (and, in fact, is unlikely to) MR. VOUDOURIS: Can you read back my question 19 reflect the presence of increased 19 to her, please. 20 pain sensation.' 20 MS. O'DELL: Dr. Allison, feel free to go 21 "And I am of the opinion that the 21 through your literature, feel free to go through 22 integration of nerve fibers into 22 your report, whatever you'd like to do. 23 23 the scarring around these mesh (The Reporter read back as follows: 24 fibers more likely than not 24 "Question: Now, you say 'I think 25 25 that might effect the function,' contributes to the pain in these Page 51 Page 53 1 patients, and would emphasize 1 and again, my question earlier 2 2 was: Can you -- an article, that there are plenty of sensory 3 3 nerves in that area that it is textbook, any of the literature 4 4 likely to affect. that you have on that chair, can 5 "Question: This is your opinion, but you point to me that supports 6 see, as an expert, you have to have your opinion on that regard?") 7 a basis for your opinion. So what's MR. VOUDOURIS: In that regard. 8 the basis for that opinion?") THE WITNESS: So in my report I say others have 9 THE WITNESS: The general principles of identified similar findings of small nerves ¹⁰ pathology, and review of cases where women are entrapped in fibrosis around mesh fibers in 11 experiencing pain and do have these small nerve 11 explants. 12 12 fibers. And then I list Klosterhalfen, 2004; 13 13 Iakovlev, 2014; and Bendavid, 2015. BY MR. VOUDOURIS: Q. Where would I find this general principle 14 Would you like me to find those articles 15 or --¹⁵ of pathology to support your statement, your ¹⁶ opinion, I'm sorry? 16 BY MR. VOUDOURIS: 17 17 A. Well, nerves -- it's the nerve -- sensory Q. No. 18 18 nerves help experience sensation, including pain, A. Okay. 19 ¹⁹ and there is not normally scarring and fibrosis Q. Those are all experts for the plaintiff, ²⁰ around those. And I think that that may affect the 20 isn't that correct? ²¹ function. MS. O'DELL: Object to the form. 22 22 Q. Okay. THE WITNESS: I don't know. I know Iakovlev 23 Now, you say "I think that might affect 23 is, but I don't know if the others are. ²⁴ the function," and again, my question earlier was: 24 BY MR. VOUDOURIS: 25 ²⁵ Can you -- an article, textbook, any of the Q. Would it surprise you to learn that they

- 1 were?
- 2 MS. O'DELL: Object to the form.
- 3 THE WITNESS: It wouldn't, and you know why,
- 4 because there aren't other -- your -- there's not
- ⁵ literature to the contrary. I mean, these are
- 6 pathologists. The pathology literature is -- there
- ⁷ isn't pathology literature that says anything other
- 8 than this.
- 9 MR. VOUDOURIS: What number are we at?
- THE REPORTER: The next one would be 7.
- 11 THE WITNESS: Dr. Longacre has not published on
- 12 this.
- 13 (Defendants' Exhibit No. 7 was marked for
- 14 identification.)
- 15 THE WITNESS: Have any of your experts
- 16 published --
- MS. O'DELL: There's no question pending,
- 18 Dr. Allison.
- 19 BY MR. VOUDOURIS:
- Q. Dr. Allison, I'll hand you what's marked
- 21 as Defense Exhibit 7.
- Do you recognize that name?
- A. You're finding all my colleagues.
- Q. You betcha we are. All the colleagues
- 25 that you're going to get up in front of a witness

13 A. Yes.

12 Dr. Vogel to review their slides?

- Q. For any type of nerve pathology?
- ¹⁵ A. Yes.

² most often.

⁵ is that correct?

- Q. By the way, in the three case specific
- 17 reports that you're going to talk about, were you

A. Yes, I consult with him for brain tumors

⁴ Dr. Vogel and consulted with him on brain tumors;

pathology, but he consults with me when he has metastatic breast cancer cases in the brain, so we

do -- we do look at cases together occasionally.

Q. Would you have -- would you feel

comfortable referring a patient or a friend to

Q. So you've -- you've reached out to

A. Well, I don't read out brain tumor

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- able to visualize nerve receptors on any of those
- 19 slides?
- A. Nerve receptors?
- 21 Q. Yes.
- A. What do you mean by that?
- Q. You don't know what a nerve receptor is?
- A. A neurotransmitter, a neuro- -- the
- 25 receptor?

- ¹ stand, in front of a jury and say are incorrect.
- A. Is that meant to intimidate me?
- ³ Q. It's not at all, it's just a fact.
- So who's authored this report that I just
- ⁵ gave you that's Exhibit 7?
- ⁶ A. Who's authored, Hannes Vogel.
- ⁷ Q. Yes.
- 8 And who is Hannes Vogel?
- 9 A. He's a neuropathologist.
- Q. And where is he a neuropathologist?
- 11 A. At Stanford.
- 12 Q. Okay.
- And is he an assistant professor, an
- ¹⁴ associate professor?
- ¹⁵ A. He's a full professor.
- 16 Q. Okay.
- Has he written books on nerves?
- A. I have not read books on nerves, so no.
- Q. Is -- do you know Dr. Vogel?
- 20 A. Yes.
- Q. Is he well regarded?
- ²² A. Yes.
- Q. If you had a question about nerves in a
- ²⁴ pathology slide, would he be one of the people you
- ²⁵ would consult?

- 1 Q. Yeah.
- A. It's smaller than I could see with a light
- ³ microscope.
- 4 Q. Okay.
- So the answer to my question would be, no,
- 6 you didn't identify any, correct?
- A. No, of course not.
- 8 Q. All you did was H&E and S100 stains?
- 9 A. H&E and S100 stains were provided to me, I
- 10 didn't perform them.
- 11 Q. Okay.
- I want you to turn to page 6 of
- 13 Dr. Vogel's report. And again, you don't dispute
- 14 that he's an expert in the field of neuropathology,
- 15 do you?
- 16 A. Of course not.
- 17 Q. All right.
- Page 6, fourth line down, can you read
 - that -- that sentence that starts with pathologists
- 20 and then has a dash?
- A. "Pathologists even those trained and
- 22 experienced in neuropathology such as myself are
- 3 not able to examine a histology section under the
- 4 light microscope and determine whether nerve twigs
- ²⁵ in the field are sensory, motor or autonomic in

Case 2:12-md-02327 Document 2189-2 Filed 05/09/16 Page 17 of 25 PageID #: 67488 Kimberly H. Allison, M.D. Page 58 Page 60 1 nature." 1 pathologists. 2 Q. Keep reading. MR. VOUDOURIS: That wasn't my question. Could 3 A. "Stains such as immunohistochemistry for you read it back, please. 4 S100 and neurofilament, which can aid in the (The Reporter read back as follows: "Question: As part of any of that ⁵ identification of parts of nerves, specifically 6 Schwann cells and axons respectfully, are incapable 6 training there, were you taught how to look at a nonneoplastic ⁷ of differentiating between sensory, motor and 8 autonomic nerves. Moreover, \$100 and neurofilament 8 tissue on a slide and correlate do not identify sensory receptors." it with clinical symptoms of pain?") 10 10 Q. Do you disagree with those sentences? THE WITNESS: There wasn't a course on pain and 11 A. No. correlation with pathology, no. It's not as common 12 O. Okav. a clinical symptom to produce a pathologic specimen 13 as other findings are, so it's for any pathologist Can we go back to Dr. Longacre again. 14 I believe we're on page 5. The second probably the minority of clinical symptoms that ¹⁵ full paragraph. we're correlating with. 16 A. Page 5 or 6? I think 6. 16 But in this case we are being asked to do Q. Okay, even better. 17 17 that. 18 A. So on page 7, second paragraph: "The mesh BY MR. VOUDOURIS: 19 19 material as itself as a foreign object and the body Q. So that the answer to my question is "no"? 20 20 reaction to the mesh do not significantly damage MS. O'DELL: She answered your question. the tissues in this anatomic location." 21 THE WITNESS: Let me think about the 22 I mean. I've seen cases where skeletal 22 specific -- more specific scenarios. 23 23 muscle is scarred and fibrosed and in the So for a patient who's experiencing bone 24 surrounding tissue with mesh kind of embedded pain and they do a bone biopsy, we would be describing the findings that would be causing the ²⁵ within it, and I think that that's damaging the Page 59 Page 61 1 bone pain, whether it be cancer or Paget's disease 1 tissue in that anatomic location. ² or osteomalacia or some other fracture. So there's So I disagree with that statement as an ³ all-encompassing statement. I think in some an example for you of a time it might correlate 4 patients the mesh has -- is causing very with pain. 5 problematic symptoms, and that reaction is -- the If a woman had a lot of pain during labor ⁶ reaction that occurs is not causing the same and she has a condition where her placenta has ⁷ symptoms in every patient, but it doesn't detract embedded too deep into the uterus, that would be a 8 from the women who are experiencing the sequelae of reason for pain. 9 the mesh eroding and causing dyspareunia. Endometriosis causes pain and when we look 10 Should I move on? under the, you know, microscope at the findings in 11 one of those patients, we diagnose endometriosis, O. Yes. 12 Before you do, I'm sorry to interrupt. which correlates with the symptom of pain. 13 13 Was it part of your medical school, your BY MR. VOUDOURIS: 14 residency, your training fellowship -- where did Q. So Dr. Longacre testifies that at Stanford ¹⁵ you go to medical school? the medical students, the residents and the fellows 16 A. New York Medical College. in pathology are not instructed or taught or told 17 that they're able to look at a nonneoplastic tissue Q. Okay. 18 As part of any of that training there, on a slide and correlate it with a clinical 19 were you taught how to look at a nonneoplastic 19 symptom, is she wrong? 20 tissue on a slide and correlate it with clinical 20 MS. O'DELL: Object to the form. 21 symptoms of pain? THE WITNESS: She may be just looking at it

23

24

25

²⁵ findings, and that's part of our training as

MS. O'DELL: Object to the form.

THE WITNESS: We're taught to correlate

clinical symptoms in general with pathologic

22

23

²² from a different angle and not thinking about

Q. You mean angle as a GYN pathologist at

examples that I just gave.

BY MR. VOUDOURIS:

¹ Stanford?

- 2 MS. O'DELL: Object to form.
- 3 THE WITNESS: She is the GYN pathologist at
- ⁴ Stanford, yes.
- 5 MR. VOUDOURIS: Okay.
- 6 Q. Keep going, please.
- A. She mentions scar form- -- this is on page
- 8 7. It's a sentence on its own without supporting
- ⁹ sentences. "While scar formation does occur, it is
- 10 typically minimal and does not lead to deformation
- 11 of the mesh."
- 12 Others have described in the literature
- 13 deformation of mesh. And from my personal
- ¹⁴ experience, looking at cases of mesh removed, I've
- 15 seen -- in one of the patients we'll talk about
- 16 today, I've seen extensive scarring and surgery --
- ¹⁷ the operative reports describe extensive scarring,
- 18 it's why this mesh is hard to remove in its
- 19 entirety. So I don't agree with the statement that
- 20 it's minimal in the patients that have issues that
- ²¹ require removal of the mesh.
- 22 Q. In the patients that you've seen that have
- 23 been sent to you by plaintiffs' counsel?
- A. The ones that have symptoms and are --
- ²⁵ yes.

1

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- ² known complication, and that there are a multitude
- ³ of factors, including infection inherent poor

1 page 7 stating it's a rare complication, but a

- 4 vascular supply, and poor or impaired wound
- ⁵ healing.
- And I guess I don't disagree with any of
- the statements she's made, but I think it is caused
- by the mesh and it's -- it is a known complication,
- so actually I agree with that statement.
 - Q. What sentence are you up to, Dr. Allison?
- 11 A. I'm on page 9, I'm trying to --
- 12 Q. Why don't we stop there, because that
- 13 talks about pelvic organ prolapse mesh implants --
 - A. Yeah.
 - Q. All right, so we're done, you've gone
- 16 through this, at least up to the page -- the
- section on pelvic organ prolapse mesh implants and
- told us all the places where you disagreed with
- Dr. Longacre, is that accurate?
- 20 A. The most -- ones that stand out most to
- 21 me, yes.
- 22 BY MR. VOUDOURIS: Okay.
- 23 Let's talk about the Thompson case.
- 24 (Defendants' Exhibit No. 8 was marked for
- ²⁵ identification.)

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- 2 A. Need examination.

Q. And --

- Q. -- what literature supports your
- 4 disagreement with Dr. Longacre?
- A. The deformation and scarring? Oh, there's 6 plenty of those.
- Let's see. 2013, Rogo Rogowski, we could
- 8 look at that one if you want, or do you want me
- just to list?
- 10 Q. Just list.
- 11 A. Okay.
- 12 Garcia-Urena, 2007; Tunn, T-u-n-n, 2007.
- 13 I have ultrasound data looking at decreases in mesh
- ¹⁴ size after insertion. Animal studies have also
- 15 shown, like Feola in 2014, F-e-o-l-a. And then
- 16 there's been literature describing the severity of
- ¹⁷ the scarring and how irreversible that can be, such
- 18 that it can continue to cause symptoms even after
- ¹⁹ it's removed.
- 20 And I list Crosby with a C, 2014;
- ²¹ Bendavid, 2014; and Rogo-Gupta, 2013.
- 22 Q. Anything else?
- 23 A. No.
- 24 Q. Continue, please.
- 25 A. She talks about mesh erosion at the end of

- BY MR. VOUDOURIS:
 - Q. Dr. Longacre (sic), we're handing you
 - ³ Defendants' Exhibit 8.
 - Can you tell us what that is?
 - A. My name is Dr. Allison.
 - Q. I'm sorry, Dr. Allison.
 - A. This is a photograph of -- it's an image
 - of a photograph I took of material that was removed
 - ⁹ from patient Thompson.
- 10 Q. And this correlates with which pathology?
- 11 A. So this is from her 2010 -- let me get my
- 12 spreadsheet. Her third, I believe, revision.
- So this is from part A, the squamous
- mucosa that was removed during the procedure where
- 15 they removed -- attempted to remove all the mesh
- that was present in the patient, because she had
- continued symptoms of erosion and urinary
- 19 Q. I'm going to hand you -- you might have it
- 20 in front of you, you're welcome to use mine, I have
- a red pen and I have a blue pen.
- 22 A. Okay.
- 23 Q. And if you can, on Exhibit 8, please
- 24 highlight for us all the things that you think are
- 25 abnormal on that slide and what you're going to

1 tell the jury about.

- A. So the most abnormal -- I mean, the mesh
- 3 material was described in their gross report and so
- 4 I don't have the tissue around the mesh, because it
- ⁵ wasn't sampled.
- 6 Q. Okay.
- If you could do me a favor, please,
- 8 because I'm limited on time, and I'd just ask you a
- 9 question about the photograph that you took, and
- 10 for you to highlight for us the abnormalities that
- 11 you're going to tell the jury about or anything
- 12 that you're going to tell the jury about, could you
- 13 do that for us, please?
- MS. O'DELL: She's answering your question, so
- ¹⁵ you just interrupted her.
- 16 THE WITNESS: The abnormalities present were
- 17 the gross presence of the mesh, and this
- 18 particular -- this was vaginal mucosa that was
- 19 removed and submitted separately from the mesh. It
- 20 was part A in the pathology report, and -- or part
- 21 B, it was a separate part from the mesh specimen
- 22 that was removed.
- 23 And so it shows minimal abnormalities,
- 24 other than the sort of denser fibrosis and scarring
- 25 down at the base of it, which is in the deepest

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- So this is the photograph that was printed ² off in the hotel I guess this morning, and the red
- ³ shows what?
- A. In the original digital image, which I'm
- sure we can provide, it shows dense fibrosis and
- scarring.
- Q. Okay.
 - So what you -- what did you circle in red?
- A. Just the deepest aspect of the tissue.
- It's very hard on this reproduction for me to tell
- sort of where that is located, but it was, per my
- report, the deepest aspect of the tissue.
- 13 O. Okav.
- 14 Would you mark for us on that what you
- have circled?
- 16 MS. O'DELL: And because it's in pink, can I
- make a suggestion that we use blue?
 - MR. VOUDOURIS: Sure, that's fine.
- 19 See, we can agree on things, Leigh.
- 20 MS. O'DELL: Our first opportunity for
- 21 agreement.
- 22 MR. VOUDOURIS: Is on pen color.
- 23 MS. O'DELL: Unbelievable.
- 24 BY MR. VOUDOURIS:
- 25 Q. Do you mind if I come over your shoulder

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- BY MR. VOUDOURIS:
- Q. Can you, with that red pen, show us --
- A. It's such a pixilated photograph, a
- 5 very --

¹ tissue.

- 6 Q. Are you telling me -- go ahead.
- A. We do have better images of this, the
- 8 images I took. I apologize, somehow the printout
- ⁹ is very pixilated, but it would be hard for anybody
- ¹⁰ to judge the reproduction here.
- 11 Q. Okay.
- 12 I haven't been provided with any other
- 13 images, so I have no idea what you're talking
- 14 about, but --
- 15 A. It's a printout of --
- 16 Q. -- we're here today -- so what you circled
- ¹⁷ in red is what?
- MS. O'DELL: I would just state for the record,
- ¹⁹ I think what Dr. Allison's trying to say is the
- 20 printer in the hotel is -- is not very good, but
- ²¹ I've provided to you a -- a PDF of the image.
- 22 BY MR. VOUDOURIS:
- 23 Q. Did you take more than one photograph?
- 24 A. No.
- 25 Q. Okay.

¹ because I can't read upside down.

- A. Sure.
- Q. Can you read that so the court reporter
- can put it down, you've written what?
- A. "Deepest aspect of tissue has dense
- ⁶ fibrosis/scar. Image is too pixilated to
- appreciate."
- Q. All right.
- 9 Which is it, dense fibrosis or scar?
- A. I think it's -- I mean, scar is composed
- 11 of dense fibrosis, so I made a slash because I
- 12 think they're both similar. Do you want me to use
- just one term?
- Q. I want you to use the term that you think
- ¹⁵ best describes what you see.
- 16 A. That's -- that's how I've described all of
- these, so that's -- that's the terms --
- 18 O. And --
- 19 A. -- I'm using.
- 20 Q. -- what's the significance of that finding
- ²¹ in the Thompson case?
- 22 A. Just that that's the aspect that was
- probably closest to the mesh. I mean, this image
- isn't -- and this particular slide is probably not
- ²⁵ representative of the pathology at play, so we're

- ¹ dependent on what tissue was put in for submission
- ² under the microscope.
- Q. Any other abnormalities on that slide that
- ⁴ you want to tell us about?
- 5 A. No.
- 6 Q. What are some risk factors for healing?
- A. Risk factors for healing, you mean poor
- 8 healing?
- 9 Q. Yes, sorry.
- A. Smoking, diabetes, obesity.
- Q. Did Ms. Thompson have any of those?
- A. She did, she had diabetes and I believe
- 13 she's a smoker. However, she didn't have any
- 14 issues immediately post-op, and that would be where
- ¹⁵ you would see the poor healing.
- Q. Do you know what her tissues looked like
- before she had the mesh inserted?
- A. The surgeon in their operative reports
- 19 don't describe any erosions or other abnormalities,
- 20 so I'm assuming, based on the records that I have
- 21 available, that they were normal.
- Q. And what's the basis for your opinion on
- 23 that?
- A. Reading the operative notes.
- Q. Anything else?

ission 1 Q. Do you know whether Ms. Thompson

- ² complained of dyspareunia before the mesh was
- 3 inserted?
- 4 A. I know she had a history of endometriosis,

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- 5 and that the dyspareunia after her procedure with
- 6 the mesh was different in nature or described as
- ⁷ cutting her partner, because of the mesh being
- ⁸ exposed. Which is not a known complication of
- ⁹ endometriosis.
- O. I believe my question was: Did she have
- 11 dyspareunia before she had the mesh inserted?
- MS. O'DELL: And she answered your question.
- 13 BY MR. VOUDOURIS:
- O. And the answer is?
 - MS. O'DELL: She answered your question.
- 16 THE WITNESS: She had pain related to
- ¹⁷ endometriosis.

15

- 18 BY MR. VOUDOURIS:
- Q. Pain anywhere else?
- A. She had pelvic pain.
- Q. So she had pelvic pain prior to having the
- 22 TVT implanted, correct?
- A. She had pelvic pain and heavy bleeding
- ²⁴ from menstrual periods, which is why I believe they
- ²⁵ did a hysterectomy as well, which took care of that

- A. I could look through the medical records
- ² again.
- Q. Did you review all of the medical records?
- 4 A. I reviewed the ones that were made
- ⁵ available to me, most of them.
- 6 Q. Most of them?
- A. Would you like me to go through them with
- 8 you or --
- 9 Q. No, I'm just asking you what you reviewed.
- A. I reviewed operative notes, a few clinic
- 11 notes, the pathology report.
- Q. Did you read any depositions?
- A. I don't recall.
- Q. Is it safe for me to assume that other
- 15 than this photograph and what you've written in
- ¹⁶ Exhibit C, that those are your findings in this
- 17 case?
- 18 MS. O'DELL: Object to form.
- 19 THE WITNESS: That based on the photographs.
- 20 BY MR. VOUDOURIS:
- Q. And what you have in Exhibit C?
- A. In Exhibit C, these are the findings in
- 23 this case, yes.
- Q. And you saw minimal inflammation?
- 25 A. Yes.

- ¹ issue.
- 2 MS. O'DELL: Dr. Allison, if you need to review
- ³ your electronic records or anything else, you can
- 4 do so
- 5 BY MR. VOUDOURIS:
- 6 Q. Did you do a differential diagnosis at all
- ⁷ in this case?
- 8 A. A differential diagnosis? No. I believe
- ⁹ that the mesh was causing her symptoms, which is
- 10 why it was removed by the surgeon. She had known
- 11 complications of mesh, repeated erosion, and then
- 12 she had issues with urinary retention and
- ¹³ dyspareunia.
- Q. You didn't see any mesh, correct?
- 15 A. The gross --
- MS. O'DELL: Object to form.
- 17 THE WITNESS: -- pathology report describes
- 18 mesh, so there was definitely mesh present.
- 19 BY MR. VOUDOURIS:
- Q. But you didn't in your pathologic
- 21 findings, did you?
- A. No. But the gross -- when you review
- 23 somebody's outside gross pathology, you read their
- ²⁴ report and you see if it makes sense, and they're
- ²⁵ documenting that there was mesh.

- 1 Q. I don't question that.
- 2 You yourself, when you looked at the
- ³ slides, you didn't see any mesh, correct?
- 4 MS. O'DELL: She answered your question and
- 5 don't tell her what to do. She's responding to
- 6 what she relied on.
- 7 THE WITNESS: They did not sample the mesh for
- 8 microscopic examination, so it was not available to
- 9 me.
- 10 BY MR. VOUDOURIS:
- Q. Are you going to be rendering any opinions
- 12 about the mesh at trial in this case to a
- 13 reasonable degree of medical certainty?
- A. Other than the gross findings and the
- 15 documentation that mesh was removed, no, not unless
- ¹⁶ additional slides become available.
- Q. And is the final tissue report that the
- 18 gross findings you're referring to, is that
- 19 Thompson PSR 01188?
- 20 A. Oh, the number -- where are you getting
- 21 the number from? Where would you like me to look,
- 22 the pathology report or the --
- Q. Bottom right-hand corner I have a Bates
- 24 stamp number.
- A. Yeah, okay.

- Page 74
- Q. And based on this gross description of the
- ² mesh, are you going to be offering any opinions to

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- ³ a reasonable degree of medical certainty?
- 4 A. Based on the gross description, yes, I am
- 5 basing part of my opinion on that, because I
- ⁶ believe that her erosions were related to the mesh
- ⁷ that was removed.
- ⁸ Q. Okay.
- Maybe there's a disconnect here. Are you
- 10 going to be saying that this mesh was degraded,
- 11 based on this report?
- 12 A. No.
- Q. Are you going to say that there was
- ¹⁴ particle loss?
 - A. I can theorize on it, but because I
- ¹⁶ haven't been provided with any material to review,
- ¹⁷ microscopically, I can't do anything other than
- 18 link by experience with these kinds of cases with
- ¹⁹ the symptoms that she had.
- Q. Are you going to say to a reasonable
- degree of medical certainty that there was any
- 22 particle loss?
- A. Particle loss? Can you describe what you
- 24 mean by that?
- Q. Particle loss from the mesh material.

- MS. O'DELL: Tell me that again, Peter, I
- ² didn't hear it.
- 3 MR. VOUDOURIS: It's PSR 01188.
- 4 MS. O'DELL: There are medical records with
- ⁵ different Bates numbers that have been produced in
- 6 this case and in all the cases, so I'm not sure
- 7 that Dr. Allison's Bates numbers are going to match
- ⁸ yours.
- 9 BY MR. VOUDOURIS:
- Q. Do you have a final tissue report dated
- 11 6-25-10?
- 12 A. I'm looking through all the material now.
- So I have S-1271-10.
- MS. O'DELL: It's Graham MDR 000840 is the
- 15 Bates number.
- THE WITNESS: Bates number, I don't even know
- ¹⁷ what that is.
- 18 BY MR. VOUDOURIS:
- Q. So this is the only record that describes
- 20 mesh, correct?
- 21 A. The --
- Q. Pathology record, I apologize.
- A. The operative note describes the scarred
- 24 mesh and removal of it. And then, yes, this part B
- 25 was the mesh, the gross description of --

- 1 A. Like the tree barking degradation?
- 2 Q. Yes.
- 3 A. I don't have the mesh.
- 4 Q. Okay.
- 5 A. Under the microscope, you're right.
- 6 Q. Are you going to say to a reasonable
- ⁷ degree of medical certainty that this mesh rope
- 8 curled or frayed?
- 9 A. No.
- MR. VOUDOURIS: Can we go off the record for
- 11 one second.
- 12 (Recess.)
- 13 (Defendants' Exhibit No. 9 was marked for
- 14 identification.)
- 15 BY MR. VOUDOURIS:
- Q. Dr. Allison, I am handing you what we've
- 17 marked as Defendants' Exhibit 9.
- Could you identify that, please?
- 19 A. This is the pathology report on Lisa
- 20 Thompson's procedure performed to remove the mesh
- 21 on 6-25-2010.
- Q. And before we took a little break, that
- 23 was the pathology report we were talking about,
- 24 correct?
- 25 A. Correct.

- Q. Do you have an idea how much time you ² spent reviewing the Thompson case?
- A. Several hours.
- Q. Now, as a lawyer when he hears the answer
- ⁵ several hours, he has no idea what that means. So
- ⁶ can you elaborate on that any further?
- A. All the records and everything? Or are
- you just talking about the slide that I reviewed
- and the pathology report?
- 10 Q. The total time you spent reviewing the
- 11 Thompson case.
- 12 A. Four to five hours.
- 13 Q. On Exhibit 8, is there anything else that
- 14 you would consider abnormal on that
- ¹⁵ photomicrograph?
- 16 A. No.
- 17 Q. Have you ever treated a woman for urinary
- 18 symptoms?
- 19 A. I'm a pathologist.
- 20 Q. So the answer to my question would be
- 21 "no"?
- 22 A. No.
- 23 Q. You don't treat patients in a clinic,
- 24 correct?
- 25 A. No.

- A. That's correct.
 - Q. And earlier in the deposition you were
 - 3 asked about mesh specimens that you had seen in

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- 4 your clinical practice, and specifically you were
- 5 asked if you knew whether those specimens were a
- 6 TVT. Is it -- is it customary for a pathologist to
- ⁷ be given the identity or the brand name of a device
- 8 when they're asked to review pathology?
- A. No, it is not.
- 10 Q. When -- would you be given -- in a
- 11 circumstance where a woman had mesh explanted,
- 12 would you be provided with the original implant
- report, prior to reviewing her pathology?
- 14 A. That would not be typical, no.
- 15 Q. And so -- is that general information
- 16 that's not been available to pathologists?
- A. Generally not.
 - Q. And you were asked a number of questions
- about the -- your role here at Stanford and the
- fact that your focus now is more on breast
- pathology. Were you trained in GYN pathology?
- 22 A. Yes, I was.
- 23 Q. Did you -- were you practicing in the area
- of GYN pathology when you were at the University of
- 25 Washington?

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- A. Yes, I was.
 - Q. And does your board certification cover
 - 3 GYN pathology?
 - A. Yes, it does.
 - Q. And are you -- even though your duties
 - 6 here at Stanford presently are focused on breast
 - pathology, is there anything that would prevent you
 - from reviewing GYN pathology and diagnose -- making
 - diagnoses based on your review?
 - 10 MR. VOUDOURIS: Objection.
 - 11 THE WITNESS: No, there's nothing that would
 - 12 prevent me from that, no.
 - 13 BY MS. O'DELL:
 - Q. You were asked a number of questions about
 - 15 can you correlate pain with findings on histology,
 - do you remember that line of questions?
 - 17 A. Yes.

25

- 18 Q. And -- is that something that you were
- 19 trained to do as a pathologist?
- 20 A. Yes, definitely.
- Q. And is that something that you have --
- 22 that you have done in your practice as a
- pathologist, and that is, review histology and make
- 24 findings or make diagnoses regarding pain?
 - A. I'm sorry, can you say it again?

- Q. And particularly, you don't treat patients
- 2 like Ms. Thompson with her complaints, correct?
- A. No. I'm a pathologist, I'm diagnostic,
- 4 not -- I don't treat patients.
- Q. Any other opinions about Ms. Thompson that
- 6 we haven't talked about?
- 7 A. No.
- 8 MR. VOUDOURIS: Okay. I think we're done with
- 9 Ms. Thompson.
- 10 MS. O'DELL: I've got a few follow-up
- 11 questions.
- 12 -0-
- 13 **EXAMINATION**
- 14 BY MS. O'DELL:
- 15 Q. Dr. Thompson -- Dr. Allison.
- 16 MR. VOUDOURIS: No one's going to get your name
- 17 right today.
- 18 MS. O'DELL: Yeah.
- Q. What type of -- of product did 19
- 20 Ms. Thompson have?
- A. A TVT-O.
- Q. And you were asked a number of questions 22
- 23 today about the TVT, but that's not the product
- 24 that Ms. Thompson was implanted with; is that
- 25 correct?

- Q. Yeah, sorry, it's probably a bad question.
- ² A. It's something I do --
- ³ Q. In your clinical practice, have you
- ⁴ reviewed pathology and made correlations to pain?
- A. Yes. I mean, we went over some examples
- 6 where a patient --
- Q. And is that generally accepted in the
- 8 field of pathology, that -- your -- the practice of
- 9 doing that?
- MR. VOUDOURIS: Objection.
- 11 THE WITNESS: Yes, we describe the pathology
- 12 findings and often -- you know, sometimes they are
- 13 in patients with pain and we might -- that might
- 14 offer an explanation for the patient's pain.
- 15 BY MS. O'DELL:
- Q. Is that process of making correlations
- ¹⁷ between pathological findings and pain in -- where
- 18 indicated, something that's generally accepted in
- ¹⁹ the field of pathology?
- 20 MR. VOUDOURIS: Objection.
- THE WITNESS: Yes. We correlate with many
- 22 symptoms.
- BY MS. O'DELL:
- Q. Dr. Allison, in rendering your opinions in
- 25 the Thompson case, did you base your opinions on

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- 1 she had removed, because of the symptoms she was
- ² having.
- 3 So the list became very short very quickly
- 4 to implicating mesh as the cause of her symptoms.
- 5 MR. VOUDOURIS: Objection, lack of foundation.
- 6 MS. O'DELL: I have no further questions,
- ⁷ Dr. Allison.
 - -0-
- 9 FURTHER EXAMINATION
- 10 BY MR. VOUDOURIS:
- Q. Dr. Allison, I have a few follow-up
- 12 questions.
- Did any of the opinions that you gave me
- 14 over the two hours that we talked going through
- 15 Dr. Longacre's report actually that dealt with TVT
- ¹⁶ and TVT-O, are any of your opinions different now
- 17 because we're talking about a TVT-O product?
- 18 A. No.
- MS. O'DELL: Object to the form.
- 20 BY MR. VOUDOURIS:
- Q. Has any urologist, gynecological surgeon
- 22 at Stanford come down to your office with a vaginal
- 23 slide after a mesh excision and asked you to
- 24 correlate any symptom with what you found on the
- 25 slide?

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- 1 the review of her medical records, the clinical and
- ² pathological literature and your training and
- 3 experience?
- 4 MR. VOUDOURIS: Objection.
- 5 THE WITNESS: Yes, I used all of that.
- 6 BY MS. O'DELL:
- 7 Q. And when you considered Ms. Thompson's
- 8 case, did you consider other possibilities for the
- 9 cause of her symptoms?
- MR. VOUDOURIS: Objection, asked and answered.
- 11 THE WITNESS: Yes. The -- yeah, earlier I was
- 12 asked about differential diagnoses, if that's what
- 13 you mean.
- 14 MS. O'DELL: Yes.
- Q. Tell us what would -- what -- as a
- 16 pathologist, what would be involved in the
- 17 differential diagnosis of a patient like
- 18 Ms. Thompson?
- A. The differential diagnosis in a patient
- 20 like her is very short, given that, as I mentioned
- 21 before, the presence of a vaginal erosion would be
- 22 very rare. And, you know, typically in diabetics,
- 23 ulcers and erosions are caused by pressure ulcers.
- 24 I'd never heard of a pressure ulcer in the vagina.
- 25 This is clearly caused by a foreign object, which

- A. No. And I doubt any pathologist has had
- ² that occur.
- 3 MR. VOUDOURIS: Okay.
- 4 MS. O'DELL: Nothing further.
- 5 (Recess.)
- 6 MR. VOUDOURIS: Going back on the record.
- ⁷ Q. Dr. Allison, I'm going to hand you what we
- 8 marked as Defense Exhibit 1, could you identify
- 9 that, please?
 - A. This is the notice of deposition.
- Q. Had you seen that prior to today?
- 12 A. Yes.

10

- Q. When did you see that?
- A. I don't recall. I saw it again this
- ¹⁵ morning, though.
- 16 Q. All right.
- There's an exhibit A attached, did you
- have an opportunity before the deposition started
- 19 to look at Exhibit A?
- 20 A. Attached?
- MS. O'DELL: I would just note for the record
- 22 that plaintiffs filed responses and objections to
- 23 Exhibit A to the notice and we reassert those
- ²⁴ objections at this time.
- MR. VOUDOURIS: When did you file those? I

- 1 never saw anything?
- 2 MS. O'DELL: Last week. What's today?
- 3 MR. VOUDOURIS: Today is Thursday, the 17th.
- 4 MS. O'DELL: Yeah. It was either late last
- week or early this week.
- 6 THE WITNESS: I don't have that.
- 7 MS. O'DELL: Yeah.
- 8 BY MR. VOUDOURIS:
- 9 Q. And Dr. Allison, as you're briefly looking
- 10 through that and take the time that you need, but
- 11 do you believe that you've -- other than the
- 12 objections stated by counsel -- provided or brought
- 13 the information that's requested?
- 14 A. Not all of it, no.
- 15 MS. O'DELL: Dr. Allison has -- has brought
- 16 information to the deposition in keeping with the
- objections that were filed on the March 15th
- 18 document No. 92 in --
- 19 MR. VOUDOURIS: Did she bring billing records?
- 20 I'm sorry to interrupt.
- 21 MS. O'DELL: We've not been billed for her work
- 22 in the Thompson matter, or Barker or Phelps for
- 23 that.
- 24 BY MR. VOUDOURIS:
- 25 Q. So you have no bills for those cases; is

1 from a person who gave me a medical report that

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- 2 should have been given to me three weeks ago last
- ³ night, but anyway, go ahead.
- MS. O'DELL: Well, she had to have surgery
- ⁵ before we could give a pathology report, that's
- 6 what happens.
- MR. VOUDOURIS: She had surgery two days ago.
- MS. O'DELL: You said three weeks ago, and she
- 9 had surgery, it takes a little while to get
- materials, as you know.
- 11 So Dr. Allison has brought with her, and
- 12 I've got in my hand, prepared to give you, Counsel,
- 13 everything responsive to Exhibit A consistent with
- 14 our objections.
- 15 MR. VOUDOURIS: That's fine.
- 16 Q. For the record, is Exhibit 2, can you
- 17 identify that, please?
- A. This is my expert report.
- 19 Q. And I believe we talked about that earlier
- 20 in the deposition, but we did -- didn't hand you
- 21 the exhibit, correct?
- 22 A. Okay. Yes.
- 23 Q. And the record will show what happened.
- 24 All right, but that's your expert report for these
- three cases?

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- A. Yes. 1
- 2 Q. All right.
- MS. O'DELL: Just note for the record, as you
- 4 know, Barker is not included in Exhibit 2, we're
- ⁵ not here for Barker at the moment. The complete
- ⁶ report for Barker, as counsel knows, is included in
- a supplemental report.
- 8 MR. VOUDOURIS: Right.
- 9 But she does talk about Barker under her
- 10 case specific opinions.
- 11 MS. O'DELL: She references the Barker case,
- 12 she says she'll supplement a report, which she did.
- 13 We did not talk about if that's Exhibit A.
- 14 MR. VOUDOURIS: Yeah, we did not.
- 15 MS. O'DELL: We did not.
- 16 BY MR. VOUDOURIS:
- 17 Q. Dr. Allison, we're going to hand you
- 18 Defense Exhibit 3, can you identify that for the
- 19 record, please?
- 20 A. This is my CV.
- 21 Q. Is it current?
- 22 A. I believe so. If it was the one that was
- 23 provided recently, yes.
- 24 Q. Why don't you take a look, that's why
- ²⁵ we're here.

1 that correct?

- 2 A. Not yet, yeah.
- Q. Is there anything as you look through this
- 4 schedule A that you believe you have in your
- 5 possession that you did not bring today?
- 6 A. I gave you my CV.
- 7 MS. O'DELL: The objections have been filed and
- 8 there's some things that -- that -- the only thing
- 9 that she's -- that's responsive to the Exhibit A
- 10 consistent with our objections are on this jump
- 11 drive, and that's the materials that were provided
- 12 to Dr. Allison. And I'll be happy to make that
- 13 available to you if you'd like.
- 14 MR. VOUDOURIS: That would be great.
- 15 THE WITNESS: So you want to know if I provided
- 16 all that on here?
- 17 MS. O'DELL: Yes.
- 18 THE WITNESS: What --
- 19 MS. O'DELL: I would just -- I think he's --
- MR. VOUDOURIS: We're doing this to make a 20
- 21 record.
- MS. O'DELL: Counsel's being a little tricky, 22
- 23 not the first time today. But....
- MR. VOUDOURIS: I object to that
- 25 characterization, counselor, considering that came

	Page 90	Page 92
1	A. Yes, it looks yes, looks current.	1
2	Q. Any additions or deletions to that	² ACKNOWLEDGMENT OF DEPONENT
3	exhibit?	3
4	A. No.	⁴ I,, do
5	MR. VOUDOURIS: I believe that's it.	⁵ hereby certify that I have read the
6	MS. O'DELL: Nothing further.	6 foregoing pages, and that the same is
7	(Whereupon, the deposition adjourned at	⁷ a correct transcription of the answers
8	3:42 p.m.)	8 given by me to the questions therein 9 propounded except for the corrections or
9	r , ,	propounded, except for the corrections of
10		changes in form or substance, if any, noted in the attached Errata Sheet.
11		12
12		13
13		14
14		15 KIMBERLY H. ALLISON, M.D. DATE
15		16
16		17
17		18 Subscribed and sworn
18		to before me this
19		¹⁹ day of, 20
20		20 My commission expires:
21		21
22		22 Notory Dublic
23		Notary Public
24		24
25		25
	D 01	
1	Page 91	
1		1 REPORTER'S CERTIFICATE
	Page 91 ERRATA	1 REPORTER'S CERTIFICATE 2 I hereby certify that the witness in the
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